

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)**

1. CERTIFICATE NUMBER: 51-R-0004
CUSTOMER NUMBER: 80

FORM APPROVED
OMB NO. 0579-0036

Virion Systems Inc
9610 Medical Center Drive
Suite 100
Rockville, MD 20850

OCT 18 2005

Telephone: (301) -309-1844

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquillizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquil- lizing drugs would have adversely affected the procedures, res- ults or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Cotton Rats	4471	12,700	580	0	13,280
S. hispidus					
S. fulviventer					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIG:

(b)(6), (b)(7)c

DATE SIGNED

10/12/05

Listing of Actual Facility Sites for Virion systems, Inc.

(b)(2)High, (b)(7)f



* Animals are housed in the vivariums of both facilities.

Noted Exceptions to the Regulations and Standards Approved by the IACUC

1. Rodents experiencing difficulty obtaining feed suspended in a wire bar lid or masticating biscuits are provided feed/fines or moistened food on the floor of the cage. The committee approved this exception to the Animals Welfare Regulations (AWRs) on June 2, 2003**
2. Waste that is, or may be perceived to be, contaminated by biohazards is disposed of using Medical Pathological Waste boxes, which remain, uncovered until sealed for incineration. The committee approved this exception to the AWRs on June 2, 2003* **
3. To produce transgenic cotton rats Animal Study Proposal (ASP 65), surgery must be conducted under a microscope. The microsurgical instruments are sanitized by immersion in 70% ethanol for at least 10 minutes, and then air drying or rinsing them with sterile water before use. The tips of the microsurgical instruments are extremely fine. Steam sterilization would ruin the instruments by causing the delicate tips to become brittle and break rendering them unable to grasp tissue properly. Ethylene oxide or gas sterilization is not available. AWRs require sterile instruments to be used. Ethanol will not kill spores and, therefore, does not constitute a means of sterilization. The instruments will be cleaned, sanitized, and stored in a manner that minimizes the risk of contamination by spore forming bacteria. Sanitization by immersion in 70% ethanol in lieu of sterilization presents minimal risk to the cotton rats. The committee approved this exception to the AWRs for ASP 65 on November 1, 2004.**
4. Use of non-pharmaceutical grade anesthetic Avertin was approved in Virion ASP 65. Avertin will not be used as the primary choice of anesthesia but will be used as a backup. The chemicals used to make Avertin are not pharmaceutical grade, therefore literature has been reviewed on using Avertin in mice and drug trials have been performed on cotton rats applying those principals to prove Avertin can be used successfully in cotton rats as well as mice. The findings were that Avertin works well, as an anesthetic in cotton rats. It would be used for vasectomizing male cotton rats and for embryonic transfer in the female cotton rat. We also wish to note that there were no adverse reactions and/or deaths caused by using Avertin as an anesthetic in cotton rats. However, the large dose size to obtain the desired level of anesthesia makes this type of anesthesia a better selection for a "back-up" anesthesia. Here we also wish to note that the cotton rats in the anesthesia trials showed no adverse reactions or discomfort due to the volume of Avertin given intraperitoneally. The preparation and storage of the chemicals that are used to make Avertin are strictly controlled to prevent chemical

degradation before and after mixing, so there will be no undesirable effects due to chemical break down. The committee approved this exception to the AWRs for ASP 65 on November 1, 2004.**

- * The materials in these boxes are items such as exam/surgical gloves, disposable drapes /toweling, gauze squares, closed tubes, large sharps containers, etc. Carcasses are kept in a carcass freezer until the disposal company arrives for pick-up. Then the Medical Pathological Waste bags and transport boxes are sealed. (The boxes are lined with biohazard bags).

** The above mentioned items that deviate from the Animal Welfare Regulations and Standards have been discussed and approved by the entire IACUC Committee. At every meeting the exceptions are discussed to see if it is necessary to continue having these items as exceptions to the regulations.

Reasoning for the Exceptions.

1. Cotton rats being wild rodents feed differently than regular laboratory rodents. They also have a different body shape. These two items sometimes constitute a need to have rodent chow or another appropriate diet easily available to them. For example, heavily pregnant cotton rats sometimes have a difficult time sitting up on their haunches to get food when they are full term. Also cotton rats have a tendency to chip or break their incisors when attempting to escape. Therefore they often will not be able to obtain food through the bars of a wire bar lid and will not be able to chew standard rodent chow, so they are given a soft, balanced rodent diet until their incisors grow out. At what time the pregnant female delivers and/or the incisors have grown back, the animal is returned to being fed from a wire bar lid.
2. The MPW transport box is prepared in advance and lined with 2 biohazard bags. Any contaminated item or perceived contaminated item is placed into the box to await pick up. Sharps are in a contained, sealed secondary safety container. Any oozing, leaking, or odiferous items must be contained and placed in a secondary container prior to placing them in the MPW box (tissues, carcasses). These items are frozen and placed in the box just prior to being removed for incineration. The reasoning behind this is to reduce the number of places where biohazard items or those perceived as such are kept prior to pick up. The boxes are vividly marked as to what they contain and are kept in an out of the way area.



(b)(6), (b)(7)c